

premises. You may be subject to a fine or imprisonment under 18 U.S.C. 1001 for any false statements you make in your request to enter the Board's premises.

#### Matters To Be Considered

##### *Discussion Agenda:*

1. Final Credit Risk Retention Rule under Section 941 of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Notes: 1. The staff memo to the Board will be made available to the public on the day of the meeting in paper and the background material will be made available on a compact disc (CD). If you require a paper copy of the entire document, please call Penelope Beattie on 202-452-3982. The documentation will not be available until about 20 minutes before the start of the meeting.

2. This meeting will be recorded for the benefit of those unable to attend. The Web cast recording and a transcript of the meeting will be available after the meeting on the Board's public Web site <http://www.federalreserve.gov/aboutthefed/boardmeetings/> or if you prefer, a CD recording of the meeting will be available for listening in the Board's Freedom of Information Office, and copies can be ordered for \$4 per disc by calling 202-452-3684 or by writing to:

Freedom of Information Office,  
Board of Governors of the Federal Reserve System,  
Washington, DC 20551.

For more information please contact: Michelle Smith, Director, Office of Board Members at 202-452-2955.

**SUPPLEMENTARY INFORMATION:** You may access the Board's public Web site at [www.federalreserve.gov](http://www.federalreserve.gov) for an electronic announcement. (The Web site also includes procedural and other information about the open meeting.)

Dated: October 15, 2014.

**Margaret M. Shanks,**

*Deputy Secretary of the Board.*

[FR Doc. 2014-24874 Filed 10-15-14; 4:15 pm]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1630-N]

#### Medicare Program; The Advisory Panel on Hospital Outpatient Payment (HOP Panel) Spring Meeting, March 9-10, 2015

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice announces the spring meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) for 2015. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) on the clinical integrity of the Ambulatory Payment Classification (APC) groups and their associated weights, and hospital outpatient therapeutic services supervision issues.

**DATES: Meeting Dates:** The first semi-annual meeting in 2015 is scheduled for the following dates and times. The times listed in this notice are Eastern Time (ET) and are approximate times; consequently, the meetings may be shorter than or last longer than the times listed in this notice, but will not begin before the posted times:

- Monday, March 9, 2015, 9 a.m. to 5 p.m. ET
- Tuesday, March 10, 2014, 9 a.m. to 5 p.m. ET

#### Meeting Information Updates

The actual meeting hours and days will be posted in the agenda. As information and updates regarding the onsite, webcast, and teleconference meeting, and agenda become available, they will be posted to the CMS Web site at: <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>

#### Deadlines

##### *Deadline for Presentations and Comments*

Presentations and Comments can be submitted by email only. Presentations or comments and form CMS-20017 must be in the Designated Federal Official's (DFO's) email inbox ([APCPanel@cms.hhs.gov](mailto:APCPanel@cms.hhs.gov)) by 5 p.m. ET, Friday, February 6, 2015. Presentations and comments that are not received by

the due date will be considered late and will not be included on the agenda. (See below for submission instructions for electronic submissions.)

**Meeting Registration Timeframe:** Monday, January 19, 2015 through Friday, February 20, 2015 at 5 p.m. ET.

Participants planning to attend this meeting in person must register online, during the above specified timeframe at: <https://www.cms.gov/apps/events/default.asp>. On this Web page, double click the "Upcoming Events" hyperlink, and then double click the "HOP Panel" event title link and enter the required information. Include any requests for special accommodations.

**Note:** Participants who do not plan to attend this meeting in person should not register. No registration is required for participants who plan to view the meeting via webcast.

In commenting, please refer to file code CMS-1630-N. Because of staff and resource limitations, we cannot accept comments and presentations by facsimile (FAX) transmission or hard copy.

#### *Meeting Location, Webcast, and Teleconference*

The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244-1850. Alternately, the public may either view this meeting via a webcast or listen by teleconference. During the scheduled meeting, webcasting is accessible online at: <http://cms.gov/live>. Teleconference dial-in information will appear on the final meeting agenda, which will be posted on the CMS Web site when available at: <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>

#### **FOR FURTHER INFORMATION CONTACT:**

Designated Federal Official (DFO): Carol Schwartz, DFO, 7500 Security Boulevard, Mail Stop: C4-04-25, Woodlawn, MD 21244-1850.

Phone: (410) 786-3985.

Email: [APCPanel@cms.hhs.gov](mailto:APCPanel@cms.hhs.gov).

Send email copies to the following address:

Email: [APCPanel@cms.hhs.gov](mailto:APCPanel@cms.hhs.gov).

**News Media:** Representatives must contact our Public Affairs Office at (202) 690-6145.

**Advisory Committees' Information Lines:** The phone number for the CMS Federal Advisory Committee Hotline is (410) 786-3985.

#### *Web Sites*

For additional information on the Panel and updates to the Panel's

activities, we refer readers to view our Web site at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

Information about the Panel and its membership in the Federal Advisory Committee Act (FACA) database are also located at: <http://facadatabase.gov/>.

#### SUPPLEMENTARY INFORMATION:

### I. Background

The Secretary of the Department of Health and Human Services (DHHS) (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) and section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside the Advisory Panel on Hospital Outpatient Payment (the Panel) regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Panel is governed by the provisions of the Federal Advisory Committee Act (Pub. L. 92-463), as amended (5 U.S.C. Appendix 2), to set forth standards for the formation and use of advisory panels.

The Charter provides that the Panel shall meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the outpatient prospective payment system (OPPS).

### II. Agenda

The agenda for the March 9, 2015 through March 10, 2015 meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Addressing whether procedures within an APC group are similar both clinically and in terms of resource use.
- Evaluating APC group weights.
- Reviewing the packaging of OPPS services and costs, including the methodology and the impact on APC groups and payment.
- Removing procedures from the inpatient-only list for payment under the OPPS.
- Using single and multiple procedure claims data for CMS' determination of APC group weights.
- Addressing other technical issues concerning APC group structure.
- Recommending the appropriate supervision level (general, direct, or personal) for individual hospital outpatient therapeutic services.

The Agenda will be posted on the Centers for Medicare & Medicaid Services (CMS) Web site approximately one week before the meeting.

### III. Presentations

The presentation subject matter must be within the scope of the Panel designated in the Charter. Any presentations outside of the scope of this Panel will be returned or requested for amendment. Unrelated topics include, but are not limited to, the conversion factor, charge compression, revisions to the cost report, pass-through payments, correct coding, new technology applications (including supporting information/documentation), provider payment adjustments, supervision of hospital outpatient diagnostic services and the types of practitioners that are permitted to supervise hospital outpatient services. The Panel may not recommend that services be designated as nonsurgical extended duration therapeutic services.

The Panel may use data collected or developed by entities and organizations, other than DHHS and CMS in conducting its review. We recommend organizations submit data for CMS staff and the Panel's review.

All presentations are limited to 5 minutes, regardless of the number of individuals or organizations represented by a single presentation. Presenters may use their 5 minutes to represent either one or more agenda items.

All presentations will be shared with the public. Presentations may not contain any pictures, illustrations, or personally identifiable information.

In order to consider presentations and/or comments, we will need to receive the following information by email only. We cannot accept hardcopy submittals.

1. An *email copy* of the presentation sent to the DFO mailbox, [APCPanel@cms.hhs.gov](mailto:APCPanel@cms.hhs.gov)
2. Form *CMS-20017* with complete contact information that includes name, address, phone number, and email addresses for all presenters and a contact person that can answer any questions and or provide revisions that are requested for the presentation.
  - Presenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter's relationship with the organization that they represent must also be clearly listed.
  - The form is now available through the CMS Forms Web site. The Uniform Resource Locator (URL) for linking to this form is as follows: <http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf>.

### IV. Oral Comments

In addition to formal oral presentations, which are limited to 5

minutes total per presentation, there will be an opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

### V. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Priority will be given to those who pre-register, and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on Federal property, must register by following the instructions in the "Meeting Registration Timeframe" section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

### VI. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present a government issued photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo identification, persons may not be permitted entry to the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.
- Foreign nationals visiting any CMS facility require prior approval. If you are a foreign national and wish to attend the meeting onsite, in addition to registering for the meeting, you must also send a separate email to [APCPanel@cms.hhs.gov](mailto:APCPanel@cms.hhs.gov) prior to the close of registration to request authorization to attend as a foreign national.

## VII. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

## VIII. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our Web site after the meeting.

## IX. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

Dated: October 7, 2014.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

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BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2004-N-0451]

### Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 037

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews ("FDA Recognized Consensus Standards"). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 037" ("Recognition List Number: 037"), will

assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

**DATES:** Submit either electronic or written comments concerning this document at any time. See section VII for the effective date of the recognition of standards announced in this document.

**ADDRESSES:** An electronic copy of Recognition List Number: 037 is available on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. See section VI for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 037 modifications and other standards related information.

Submit written requests for single copies of the document entitled "Modifications to the List of Recognized Standards, Recognition List Number: 037" to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-847-8149.

Submit electronic comments on this document to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring, MD 20993, 301-796-6287, [standards@cdrh.fda.gov](mailto:standards@cdrh.fda.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows

FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The notice described how we would implement our standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains HTML and PDF versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

#### II. Modifications to the List of Recognized Standards, Recognition List Number: 037

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. We will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. We will use the term "Recognition List Number: 037" to identify these current modifications.

In Table 1, we describe the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.